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Approach on how to prioritise and address petroleum and coal stream UVCB substances for further work under the Roadmap for SVHC identification and implementation of REACH Risk Management Measures.

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1. Introduction

The Substances of Very High Concern (SVHC) Roadmap to 2020 gives priority to substances with SVHC properties which are registered for uses within the scope of authorisation. Among the substance groups falling under the scope of this Roadmap are UVCB¹ petroleum and coal stream (PetCo) substances. These substances have been omitted from many earlier screening exercises and postponed from consideration for potential further regulatory action due to the complexity in defining and assessing them.

The Roadmap notes that there is a need first to develop an approach how to address these substances before starting their systematic assessment. The PetCo Working Group was established in 2015 in order to support the development of an approach to prioritise for further work those substances with a need for further regulatory action and to plan the practical implementation of this approach as required by the SVHC Roadmap.

The general objective of the approach is to provide advice on how to best prioritise and address the specificity of these substances in the context of regulatory processes (e.g. from the perspectives of substance identification and/or hazard assessment through the different regulatory processes). The aim is also to improve the quality of dossiers of all PetCo substances in order to facilitate the identification of substances of high but also low concern from a regulatory risk management perspective.

More specifically the approach aims to:

- Identify which substances fall within the remit of the PetCo approach
- Define priorities for further work (e.g. high priority substances having widespread use within the scope of authorisation for which there are already constituent(s) of concern identified and regulatory action can already be taken)
- Plan for each subgroup of substances the implementation of the approach i.e. the different actions foreseen by the different actors as well as a timeplan of those actions.

¹ substances of very complex and variable/partly undefined composition

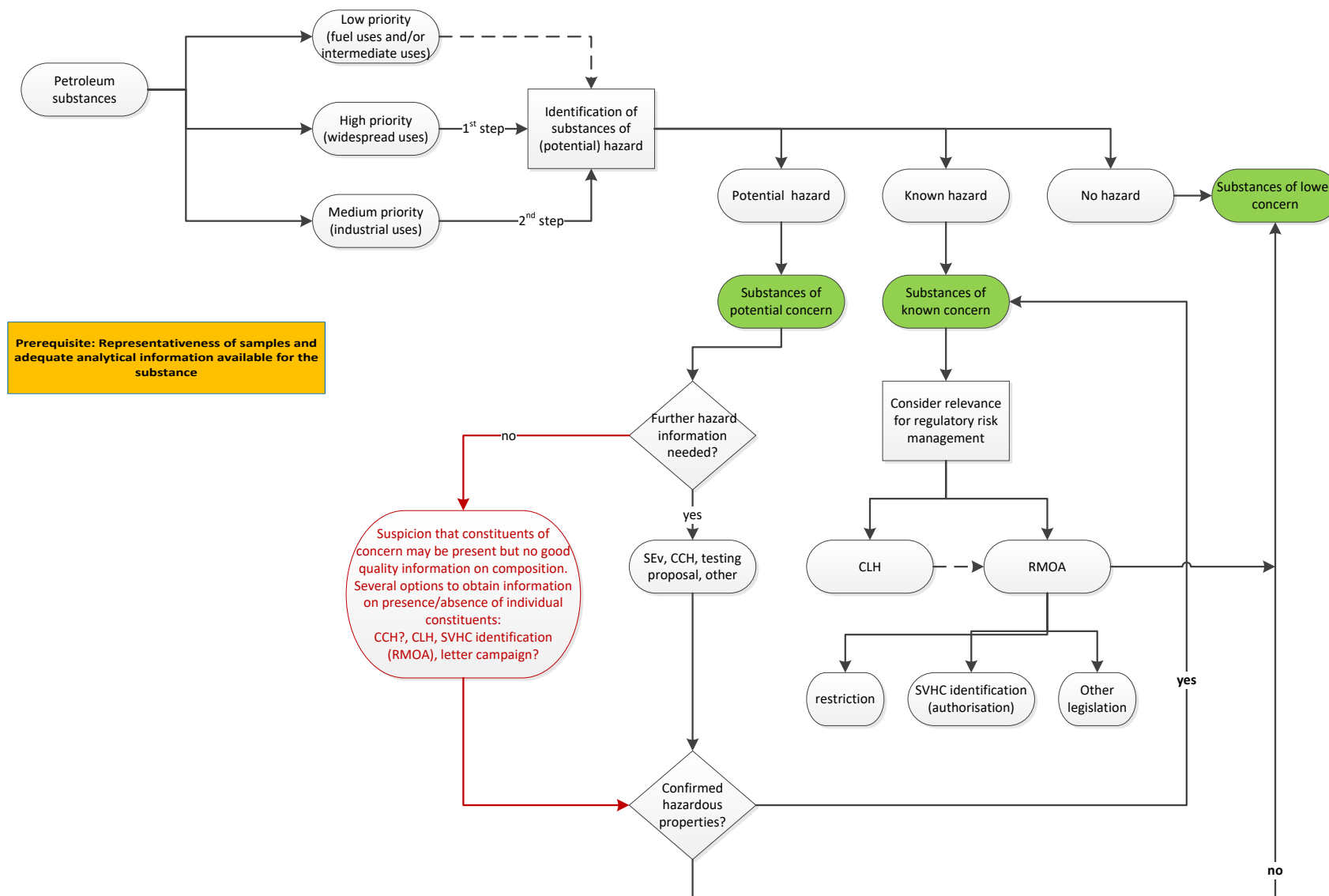


Figure 1: Schematic representation of the approach on how to identify and assess PetCo substances.

2. Substances falling within the scope of the approach: The PetCo inventory

The current approach applies to petroleum and coal stream substances of very complex and variable/partly undefined composition (UVCBs). This excludes petroleum and coal stream substances that are not UVCBs as they can normally be addressed with the available standard approaches (e.g. well defined multi-constituents).

Most petroleum and coal stream substances are managed by the following consortia:

- Petroleum stream substances (Concawe)
- Coal stream substances (R4CC)
- Lower Olefins and Aromatics (LOA)
- Hydrocarbon solvents (HSPA)
- Higher Olefins & Poly Alpha Olefins (HOPA)

In addition the approach will also cover UVCB substances of petroleum or coal origin which do not belong to any consortia, so called "orphan" substances.

The list of substances falling under the approach is available in the PetCo inventory. The PetCo inventory needs to be kept up to date. Industry sector associations will ensure regular update of the PetCo inventory by notifying any change on the status of substances falling in the inventory to ECHA (e.g. deletion of substances from the PetCo inventory, change of supporting consortium with clarification of uses, change of identifiers). The update of the PetCo inventory should be done on a regular basis and as indicated in individual implementation plans and the updated version made available to both stakeholders and authorities. Changes in the PetCo inventory have to be reflected in update of registration dossiers.

Recycled substances are not directly in the scope of the approach even though some may be covered already when they are considered to be the same registered substance as those subject to the approach.

3. Targeting work to substances that matter most

As for any substance covered by the REACH Regulation, priority should be given to those PetCo substances that matter most, meaning those that can potentially impact human health and the environment. This means that there needs to be a potential for exposure of humans or the environment to the substance and a potential for the substance to cause adverse effects (hazard potential) to human health or the environment.

Because of the complexity of the PetCo UVCB substances (complexity in composition, testing difficulties, limited data and therefore challenging hazard assessment), it appears most efficient to find ways to prioritise actions on those substances that matter most instead of addressing all of them via for instance compliance check or substance evaluation. Therefore PetCO substances are first prioritise on the basis of their uses before considering in a second step the hazardous properties of the substances as such and/or their constituents.

Due to the specificities of each consortia in terms of substances and uses, the prioritisation will be conducted separately for each consortium. The 'orphan' substances will be grouped together and the same prioritisation principles will be applied by ECHA. The different steps of the prioritisation and the actions derived from it must be included in the implementation plans.

3.1. Identify groups of substances of higher priority based on information on uses

For every consortium (and the 'orphan' group) of PetCo substances, priority will be assigned initially on the basis of information on uses as follows:

- Substances with **low priority** for further work for which the only uses reported are as intermediates or fuels
- Substances with **medium priority** for further work having no widespread uses but only industrial uses (other than intermediate and fuel uses)
- Substances with **high priority** for further work having widespread uses: defined as substances having at least one professional or consumer use (other than fuel uses) or one article service life.

Industry sector associations will ensure that relevant information on uses for each individual substance is available to ensure adequate prioritisation of the substances. Proper planning of the gathering of information of uses is available in individual implementation plans when relevant. The implementation plans also include update of the dossiers by registrants however if the information is available in a comprehensive form the prioritisation of substances can start before the update of registration dossiers are received.

Substances with high priority from a use perspective are the first to be further prioritised for identification of (potential) hazard (Figure 1). The learnings gained on those substances is to be used on medium priority and low priority substances. However it may be that medium priority substances need to be considered at the same time if the uses are of relevance and hazard properties are known meaning that further regulatory action can already be identified and initiated.

Substances with intermediate uses only are low priority substances. For some substances not used under strictly controlled conditions, releases particularly to the environment may nevertheless be relevant. However REACH may not be the right regulatory tool for those substances even though it could help generate data for other regulatory instruments (e.g. SVHC identification for substances with PBT and/or ED properties).

3.2. Substance identification and analytical composition

The different steps described in section 3.3 for identifying substances of concern or lower concern and determining which regulatory actions need to be taken assume that **representative information on the composition of each individual substance is available** and reported in Substance Identity Profiles (SIPs) in order to allow proper hazard assessment and not only sameness assessment.

If such information is not available then the prioritisation approach will rely on assumptions and thus decisions by authorities to work further on substances will be taken based on those assumptions. Different tools may be used to obtain such information if not yet available in registration dossiers as exemplified in Figure 1 (e.g. CCH, letter campaign). One action could be for instance that in absence of analytical information authorities may decide to prepare harmonised classification and labelling dossiers or Annex XV dossiers for SVHC identification for single constituents and it would be then on registrants later on to demonstrate that their substance(s) do not contain those specific constituents. It will be important when applying the approach to consider which approach would be the most efficient in terms of resources for all parties.

3.3. Identify substances with (potentially) hazardous properties

The uses-based prioritisation is further refined based on available information on the (potential) hazardous properties of the substances.

Priority is given to those substances with hazardous properties relevant for identification of SVHCs as defined in Article 57 of REACH i.e. persistent, bioaccumulative and toxic (PBT)/very persistent and very bioaccumulative (vPvB), endocrine disruptor (ED), carcinogenic, mutagenic, reprotoxic (CMR) and other equivalent level of concern².

Substances are grouped as follows:

- **Substances of known hazard:** substances for which there is clear indication that the substance or one (or several) of its constituents is a known hazardous chemical at regulatory relevant concentration(s)
- **Substances of potential hazard:** substances for which the information available suggests that the substance or one (or several) of its constituent(s) is suspected to be hazardous. For these there is a need to further investigate the hazardous properties.
- **Substances of no known hazard:** substances for which the information currently available does not indicate the presence of known or potential hazard as defined above and below.

A substance (or constituent) is considered to be of "known hazard" in the following cases:

- harmonised classification and labelling (or formal endorsement procedure for C&L proposal so far advanced that acceptance of proposal and entry into CLP Annex VI is certain) exists for the substance/constituents. The focus will be on substances/constituents classified as CMR category 1A/1B
- the substance/constituent has been identified as a PBT/vPvB or as a substance of equivalent level of concern (e.g. ED) and is included in the Candidate List.
- specific constituents of a substance included in the Candidate List have been identified as PBT/vPvB and/or ED by the Member State Committee.

Substances of "potential hazard" are substances for which potential human health and/or environmental hazardous properties have been identified. The potential to be hazardous may refer to the substance itself or to the presence of potential hazardous constituents.

Substances will be examined by authorities from both human health and environmental hazard perspectives. Information on (potential) hazardous properties will be gathered by industry sector associations and authorities and substances of (potential) hazard identified (see Figure 2).

² The focus will be first on those substances having potential or known PBT/vPvB, CMR and ED properties however additional properties of equivalent level of concern may be considered on a case by case basis (e.g. STOT RE).

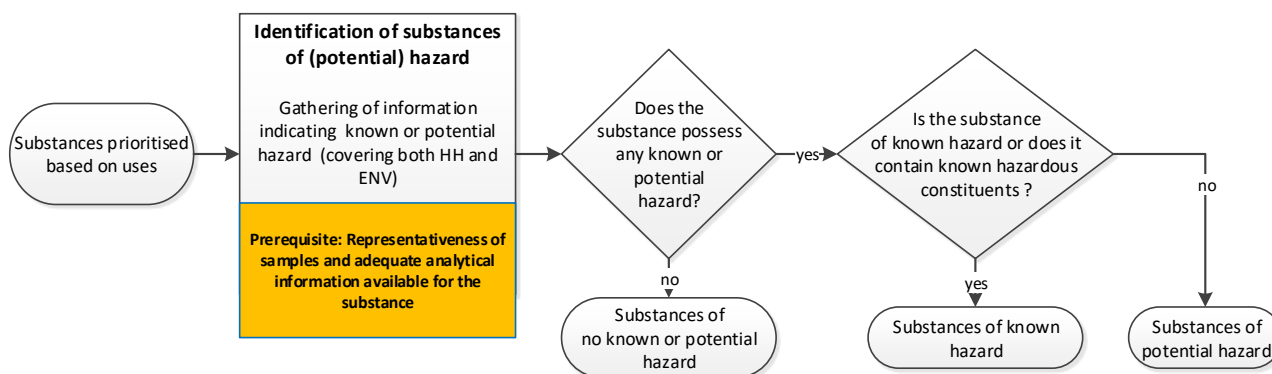


Figure 2. Identification of groups of substances based on hazard information (HH: Human Health; ENV: environment)

The prioritisation approach developed for the identification of substances of (potential) hazard is further explained in the hazard prioritisation document.

Substances identified as having known or potential hazard will be considered as substances of concern and will be further considered by Authorities for regulatory action, whereas those substances with no hazardous properties will be considered as substances of lower concern and not prioritised further for action for the time being.

Once all high priority substances with widespread uses are categorised as described above i.e. either no action or further regulatory action needed, the same approach can be applied to the other priority group of substances starting from medium priority (industrial uses only). Before doing so Authorities together with Industry sectors associations in the context of PETCO should first assess whether the hazard information obtained on the high priority substances is sufficient to conclude on the hazardous properties for any of the medium priority substances (e.g. by read-across or category approach).

4. Consider the need for further regulatory action

4.1. Substances of concern

4.1.1. Substances of known concern

The scheme below (Figure 3) refers to substances of known concern assuming that adequate information is available on the composition of the substance for all registration dossiers.

Substances of known concern are substances having widespread uses and known hazardous properties (of the substance itself or due to the presence of one or more hazardous constituents).

- For substances that are of concern on their own (e.g. UVCB PetCo substance classified as CMR cat 1A/1B) the next step is for authorities to consider further regulatory risk management (e.g. Risk Management Option Analysis (RMOA))
- For substances with known hazardous constituents (e.g. the constituent is classified as CMR cat 1A/1B or identified as PBT/vPvB) the following 2 steps should be considered by authorities:

1. Consider whether the constituent concentration³ is relevant for initiating further regulatory risk management.

Different situations may arise depending on the variability in composition observed, particularly regarding the presence/absence of constituents with hazardous properties:

- The concentration of the individual relevant constituent(s) is always above the relevant regulatory thresholds when compositional variation is taken into account (e.g. for classification of the substance as CMR or identification as PBT/vPvB); the substance is considered as a **substance of known concern** and the need for further regulatory risk management actions should be considered by authorities.
 - The concentration of the individual relevant constituent(s) is always below the relevant regulatory thresholds when compositional variation is taken into account; the substance is considered a **substance of no known concern** (provided that no additional potential concerns exist).
 - The concentration of the individual relevant constituent(s) is sometimes above relevant regulatory thresholds when compositional variation is taken into account; the substance is considered as a **substance of concern** and the need for further regulatory risk management action should be considered by authorities for the variants of the substances (e.g Substance X containing a specific constituent Y above the regulatory threshold) for which the regulatory thresholds are exceeded.
2. Consider whether there is any added value in clarifying additional hazardous properties before going for further regulatory risk management.

For instance a substance for which additional PBT concern would have been identified whereas it already contains a known constituent classified as CMR cat 1A/1B. In that specific situation it may be worth identifying the additional PBT concern before going to further regulatory risk management as this will have an impact on the proposed actions. If the additional concern would have been on another human health hazard than CMR then the added value of delaying the regulatory risk management action for clarifying this additional concern can be questioned. Figure 3 below summarises the different situations.

For substances identified for further regulatory risk management a Risk Management Option Analysis (RMOA) will be prepared by authorities as for any other substance.

The first cases of substances proposed for regulatory risk management will be used to build a better understanding on how to best regulate those substances and learnings will be applied to the next substances.

³ Note that it is difficult to further define concentration in that context due to variability in composition of PetCo substances and as further highlighted with the different situations that can be encountered.

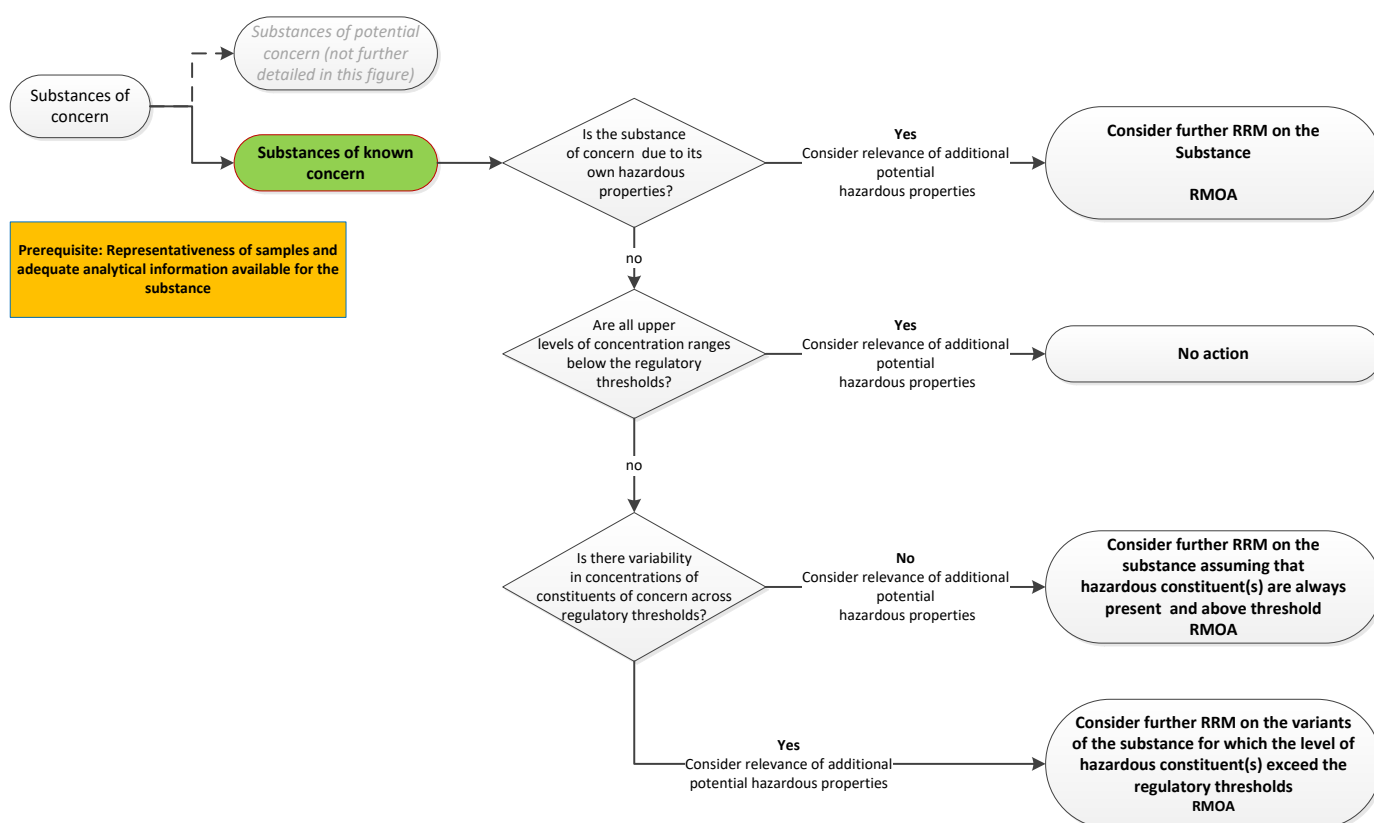


Figure 3: Elements to consider for substances of known concern

4.1.2. Substances of potential concern

Substances of potential concern are substances having widespread uses and potentially hazardous properties (due to the substance itself or due to the presence of one or more potentially hazardous constituents). Substances of potential concern include those substances for which there is no clarity on the presence/absence of constituents of known concern.

The following situations can be expected:

- The substance or one (or several) of its constituent(s) is of potential concern and there is enough hazard information available to clarify the concern and to prepare for instance either a dossier for SVHC identification⁴ in case of PBT/vPvB and ED properties or a CLH dossier for CMR and sensitising properties. However there are uncertainties on the presence/absence of the constituent(s) of concern as the analytical information is of low quality.
- The substance or one (or several) of its constituent(s) is of potential concern and there is a need to generate further hazard information in order to conclude on its hazardous properties. The best way to obtain necessary information should be considered (e.g. informal contact with registrants and voluntary commitment to generate the information or the use of regulatory tools such as Compliance Check or Substance Evaluation).

⁴ After RMOA

4.2. Substances of lower concern

The substances falling in this group are:

- Substances with absence of known or potential hazardous properties
- Substances with potentially hazardous properties clarified after generation of further data as being non hazardous
- Substances for which the outcome of the risk management option analysis (RMOA) indicate that there is no need for action at this point in time.

4.3. Consider the added value of the work done on the highest priority group of substances for lower priority substances

Data and experience gained by better understanding the hazardous properties and also potential regulatory risk management under REACH of high priority substances should be considered before assessing the medium priority substances (based on uses).

5. Planning of activities

The approach proposed above is to be applied to all consortia falling under the scope of the PetCo working group (e.g. petroleum substances, coal stream substances, etc.) as well as to 'orphan' substances.

Planning of foreseen activities for each consortium is available in their implementation plans with indicative timelines. The plans will have to be regularly updated to take into considerations the new information generated.

Each individual plan includes update of registration dossiers with the information generated.

The different actions foreseen will be performed either by industry sector associations, individual registrants and/or authorities and responsibilities are further detailed in the annexes. For the orphans ECHA will contact individual registrants.

The PetCo Working Group will ensure the follow up and tracking of the different actions agreed and planned as documented in the implementation plans as well as communication between Authorities and stakeholders.

Substances falling under PetCo will be clearly identified based on the PetCo inventory in ECHA's database and will not be proposed by ECHA for instance as individual substances to be manually screened by Authorities in the context of the common screening. However, once a substance is identified for further regulatory action, either for generation of additional information, targeted assessment or for particular regulatory risk management (e.g. RMOA, CLH, SVHC identification) the substances will be considered as any other substance and will be followed up by the relevant groups (e.g. PBT/ED EG). The outcome of the assessment will be tracked by the PetCo Working Group to ensure that the learnings from one substance is used to better understand the other substances.

The aim of the approach is to find ways to prioritise and address PetCo substances, but also to increase the general understanding of the concerns associated with those substances which should be reflected eventually in the update of registration dossiers.